## REMARKS

This Amendment is fully responsive to the final Office Action mailed June 19, 2009. It is respectfully submitted that the claims contain limitations that patentably define over the references cited by the Examiner, for the reasons discussed in these remarks. Therefore, reconsideration and allowance of the pending claims is appropriate and respectfully requested.

### *Objection to Drawings*

The Office Action (page 2) objects to the drawings because the reference number "191" for the medical device is not recited in Figures 2-4B. Accordingly, replacement drawing sheets are submitted with this response, amending Figures 2, 3, 3A and 4A (but not Figures 3B and 4B) to incorporate adding the reference number 191. It is believed that the amendments to these Figures is sufficient to obviate the objection to the drawings.

### *Amendments to Abstract and Specification*

The Office Action (page 2) objects to the Abstract. The Abstract has accordingly been amended in this response to obviate the objection.

The Office Action (page 3) objects to the disclosure in the specification because of informalities in the priority claim paragraph. That paragraph has accordingly been amended in this response to obviate the objection. One additional amendment to the disclosure is made herein to correct a typographical error.

### *Claim Rejections Under 35 U.S.C. § 112*

The Office Action (pages 3-4) rejects claims 4, 5 and 11-18 under 35 U.S.C. § 112, ¶ 2 as being indefinite. The claims have been amended to obviate these rejections.

### *Claim Rejections Under 35 U.S.C. § 102*

The Office Action (pages 4-7) rejects claims 1-8, 10-17 and 19 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,078,140 to Kwoh (hereafter "Kwoh"). This group of rejected claims contains three independent claims: 1, 10 and 19. Those claims respectively recite as follows:

- in the system of **claim 1**, "the guide apparatus comprising . . . a gripping area . . . adapting the guide apparatus for manual gripping by an associated operator . . . [and a] holding area being operative to translate the medical device along said selected linear path in response to manual force applied by the associated human operator at said gripping area during insertion of the medical device";

- in the method of **claim 10**, providing "a guide apparatus including . . . a gripping area . . . adapting the guide apparatus for manual gripping by an associated operator . . . [and a] holding area being operative to translate the medical device along said linear path in response to manual force applied by the associated human operator at said gripping area during insertion of the medical device"; and

- in the guide apparatus of **claim 19**, a "gripping area adapting the guide apparatus for manual gripping by an operator . . . [and a] holding area being operative to translate the medical device along said selected linear path in response to manual force applied by the operator at said gripping area during an insertion of the medical device."

Thus, each of the three rejected independent claims recites a guide apparatus having a holding area operative to translate a medical device along a linear path in response to manual force applied by a human operator manually gripping a gripping area of the guide apparatus during insertion of the medical device. It is requested the rejections based on an anticipation of claims 1-8, 10-17 and 19 be reconsidered and withdrawn because Kwoh does not disclose that claim limitation.

This exemplary feature of the invention is described in the present application as the second step in a two step process for inserting a medical device into a patient. In the first positioning step, the guide apparatus is maneuvered to place the medical device is a position and/or orientation defining a physical path coincident with a planned trajectory. See Application, at page 7, line 24 to page 8, line 7 and at page 11, line 30 to page 12, line 14. This positioning step may be accomplished manually, but is preferably performed by executing a program to operate a robotic arm and / or the subject support. See id.

In the second insertion step, and referring to the embodiment of Figure 3 reproduced here (as amended herein), the guide apparatus 200 is manually gripped by an associated interventionist at a gripping area 230. See Application, at page 8, lines 14-16 and at page 12, lines 14-18. A medical device holding area 240 holds an associated interventional implement 191 for motion relative to the patient 20 along a selected linear path P for insertion into the patient. See Application, page 8, lines 16-20. That linear path motion P occurs in response to manual force provided by the associated interventionist at the gripping area 230 to perform a medical device insertion. See Application, page 8, lines 20-23. Thus:

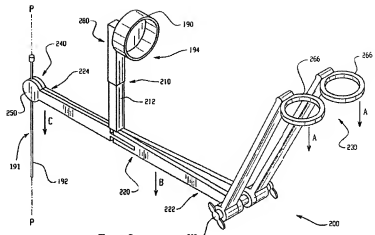


Fig. 3

> In that manner, force applied by the interventionist at the gripping area 230 in the direction A urges the main body portion 220 to translate along a linear path B as constrained by the single degree of freedom connector portion 210. This in turn causes the holding area 240 to similarly move in a linear path C.

See Application, page 8, lines 23-27. This single degree of freedom may preferably be provided by a connector portion 210 comprising a linear slider joint, or a prism joint, although other embodiments are possible. See Application, at page 8, lines 29-31 and at page 10, lines 15-19.

One benefit of such an apparatus is that it allows the interventionalist to insert the interventional implement 191 into a patient without placing his or her hands in the x-ray beam, while at the same time receiving tactile feedback during insertion. The application describes how this is an advantage over prior art "automated robot-like mechanical systems":

> A proposed approach to solving the aforementioned problem [i.e. undesirable x-ray exposure to the interventionalist's hands] involves the use of automated robot-like mechanical systems which allow the interventionalist to manipulate the biopsy needle remotely while keeping hands clear of the x-ray beam. However, such systems typically reduce or eliminate the tactile sensations (e.g., pressure and tension forces, shear, and/or moment on the needle) otherwise available to an interventionalist directly manipulating the needle. This is disadvantageous in that interventionalists typically obtain useful information from these tactile sensations and rely upon it regarding the

procedure. For example, they are often able to feel the progress of the needle as it transitions between different tissue types, makes contact with bones, punches through skin, etc. The interventionalists generally desire this "feel" as they perform biopsies. To trained personnel, it serves as an additional indication of the needle's location.

See Application, page 2, line 28 to page 3, line 15.

Turning to Kwoh, it too describes a two step process for inserting a medical device into a patient. In the first positioning step of Kwoh, a surgeon maneuvers a robotic arm 1 to designate an appropriate entrance point on the skull, and also determines an approximate entry trajectory of a probe by directing a probe holder 21. See Kwoh, col. 6, lines 57-67, and Figures 1 and 4 (reproduced here). As noted in the Office Action, these maneuvers may be accomplished either by pushing buttons on a manual control unit of the robotic arm 1 ("controller" in Figure 1) or by setting the robotic arm 1 to the "free" mode and manually manipulating the robotic arm 1. See Kwoh, col. 6, line 67 to col. 7, line 2. Once a rough alignment is thus achieved, then the positioning step continues:

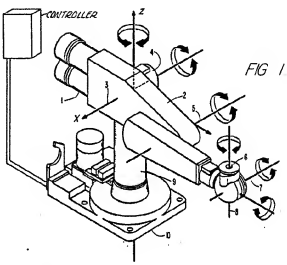
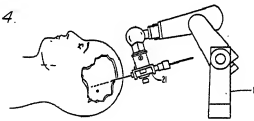



FIG. 4.



> Stereotactic computer software designed in known fashion . . . is then used to activate the means for controlling the robotic arm 1, e.g., a host computer, to direct the robotic arm 1 to align the probe holder 21 with the trajectory determined by the entrance point and the target. Initially, the robotic arm 1 is driven in such a manner as to be a safe distance away from the head. By pushing two buttons on the manual controller, or by typing commands into a keyboard that interacts with the computer software, the surgeon may control the robotic arm 1 so that the probe holder 21 moves in or out along the trajectory, as shown in FIG. 5, as close to the head as desired. The surgeon can use the buttons on the manual control unit of the robotic arm 1 to alter the trajectory. The stereotactic computer software maintains the trajectory line of the probe holder 21 constantly pointing at the target, as shown in FIG. 6.

See Kwoh, col. 7, lines 3-28 (emphasis added). Thus, at the end of the positioning step of Kwoh, the robotic arm 1 and probe holder 21 are properly positioned for insertion of the probe into the patient.

Then, once the final probe trajectory is determined to the surgeon's satisfaction, there is a second insertion step. In the insertion step of Kwoh, the robotic arm 1 is "locked . . . by clamping its end effector with the external clamp or stand 71 as shown in" Figure 7 (reproduced here). See Kwoh, col. 7, lines 52-62. Once the arm 1 is locked by the clamp 71, the surgeon "inserts the probe 72 manually." See id. It is not clear from the disclosure of Kwoh what the "manual" probe insertion entails. However, there appear to be only two possibilities.

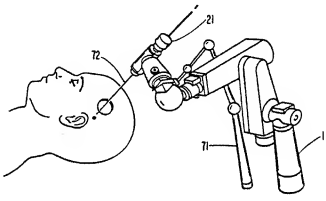


FIG. 7.

In the first and most likely interpretation, the "manual" insertion of the probe in Kwoh refers back to the electronic "manual controller" of the robotic arm 1 shown in Figure 1 of Kwoh. However, in that event, Kwoh is missing the claim limitation requiring translation of the inserted medical device in response to a manual force applied by a human operator manually gripping a gripping area of a guide apparatus. Rather, use of the electronic "manual controller" entails electronically operating intervening motors and gears to insert the medical device. This is the exact kind of "automated robot-like system" which does not provide a tactile response to the user, and which the present invention is designed to improve upon.

In a second interpretation of Kwoh, the "manual" insertion of the probe corresponds to the "free" mode of the robotic arm 1, whereby it is operationally disconnected from the electronic "manual controller." In that event, however, there is nothing to prevent the probe holder from moving away from a linear path during insertion of the probe. Disconnection from the controller prevents the motors and gears from maintaining the linear path. And, it is clear from a comparison of Figure 7 and Figure 1 that the clamp 71 of Figure 7 does absolutely nothing to constrain movement of the rotatable joints 6, 7 and 8 of the robotic arm 1. Thus the clamp 71 is unable to

maintain a linear insertion path. In short, even if the "manual" insertion of Kwoh does refer to the "free" movement mode, there is no provision in Kwoh to constrain the "free" movement of the probe to a linear insertion path.

For at least these reasons, Kwoh does not disclose a guide apparatus having a holding area operative to translate a medical device along a linear path in response to manual force applied by a human operator manually gripping a gripping area of the guide apparatus during insertion of the medical device. Therefore, Kwoh does not disclose each and every limitation of claims 1-8, 10-17 and 19, and the rejection of these claims as being anticipated by Kwoh should be reconsidered and withdrawn.

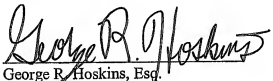
***Claim Rejections Under 35 U.S.C. § 103***

Claims 9, 18 and 20 respectively dependent from independent claims 1, 10 and 19. The Office Action (pages 7-8) rejected each of these dependent claims under 35 U.S.C. § 103(a) as being unpatentable over Kwoh (discussed above in connection with the independent claims) in view of U.S. Patent No. 3,893,813 to Johnson (hereafter "Johnson"). In each rejection, Kwoh was relied upon as teaching the limitations of the parent independent claims, and Johnson was cited as teaching the limitations of claims 9, 18 and 20. For at least the reasons identified above, however, Kwoh does not anticipate independent claims 1, 10 and 19. Johnson does not cure the deficiency of Kwoh. Thus, it is respectfully submitted that the obviousness rejections of the dependent claims should be reconsidered and withdrawn.

***Conclusion***

This Amendment is fully responsive to the Office Action mailed June 19, 2009. It is respectfully submitted that the claims contain limitations that patentably define over the references cited by the Examiner, for the reasons provided in the remarks above. Therefore, reconsideration and allowance of the pending claims is appropriate and respectfully requested.

Respectfully submitted,



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